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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,609	03/30/2004	Paul Re	SCAN-1 CON	3229

7590
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EXAMINER

BACHMAN, LINDSEY MICHELE

ART UNIT	PAPER NUMBER
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3734

MAIL DATE	DELIVERY MODE
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04/16/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/812,609	Applicant(s) RE ET AL.	
	Examiner LINDSEY BACHMAN	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,9,16,17 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,9,16,17 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1 February 2008 has been entered.

Response to Arguments

In response to Applicant's arguments that Mulhauser's device cannot not always have a bowed, proximal end profile, this is not persuasive because Mulhauser states that the unstressed implant can be formed with slight convexity or concavity (column 3, lines 60-61). Regarding, Applicant's arguments that since the cover is formed of mesh or pliable tissue it could not extend further proximally than the proximal end of the annular frame, Applicant does not state why they assert this and Examiner does not understand why it couldn't, especially since Mulhauser explicitly states that the unstressed implant could be *formed* with a slight convexity of concavity.

Regarding the rejection to Claim 20, Applicant has not presented any arguments regarding Kaikkonen.

Claim Rejections - 35 USC § 112

Claim 1 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1 and 20 recite "a solid shell-like metal cover portion." Applicant's disclosure does not state that the cover is made of metal, only a solid, shell-like cover.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 9, 12, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mulhauser, et al. (US Patent 6,267,772) in view of Frey et al. (US Patent 4,776,328) and in further view of Kaikkonen et al. (US Patent 6,533,454).

Claims 1 and 3: Mulhauser'772 teaches a tissue repair device (10) containing a body containing an annular frame portion (14) and an integral, solid cover portion (12; column 4, lines 51-59) disposed within the frame portion (see side view in Figure 2b). Further, the device contains legs (22). Mulhauser'722 teaches that the cover portion can be bowed proximally (column 3, lines 60-61). Mulahauser'772 does not teach that that the cover portion is made of metal or that the legs are several times longer than the thickness of the body, nor do the legs contain central channels.

Frey'328 teaches legs (1) that contain a central channel (11) opening on the proximal side of the device and closed at the distal end. Further, the legs contain with a distal end portion that extends beyond the periphery of the tapered portion immediately proximal to the tapered section in order to prevent withdrawal (column 2, line 61 to column 3, line 3). It would have been obvious to one skilled in the art at the time the invention was made to modify the device taught by Mulhauser'772 with the legs taught by Frey'328 because they are longer and capable of engaging the tissue better.

Mulhauser'772 in view of Frey'328 do not teach the use of a metal cover member. However, it is old and well known to use flexible metal cover members to facilitate healing, as described by Kaikkonen (column 1, lines 65 to column 2, line 6), because they are strong and tough and also capable of being ductile so they can be deformed and shaped to correspond to the surface topography of the tissue being fixed.

It would have been obvious to one of ordinary skill in the art to modify the cover member taught by Mulhauser'772 in view of Frey'328 in order to have a strong and tough cover member that is also capable of being ductile.

Claim 9: Mulhauser'772 teaches attaching the cover to the frame using insert molding (column 4, lines 26-34).

Claim 12: Mulhauser'772 teaches a shell member (14) and struts (22) that extend from the center of the shell member (center of outer frame circumference).

Claim 16: Mulhauser'772 teaches that the fabric can be made of absorbable material (column 4, lines 35-51). Further, Noiles'089 teaches that his device is made of bioresorbable material because this is desirable for physiological reasons (column 1, lines 1-23).

Claim 17: Mulhauser'772 teaches that the cover can be a material which promotes cell growth (column 4, lines 35-51).

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mulhauser'772 and Kaikkonen et al. (US Patent 6,533,454).

Claim 20: Mulhauser'772 teaches a method of repairing a cartilage defect that includes providing a body for disposition against a bone with a defect in which the device contains elongated leg structures (22) for disposition into the bone and bring the distal surface of the device into contact with the bone (column 7, lines 13-35 and column 3, lines 39-41). Mulhauser'722 teaches that the solid, cover portion (12; column 4, lines 51-59) can be bowed proximally (column 3, lines 60-61). Mulhauser'772 does not teach that the legs are several times larger than the thickness of the body, nor do

Art Unit: 3734

the legs contain central channels that extend partially through the legs, nor is the cover member made of metal.

Kaikkonen'454 teaches a device for tissue fixation with legs (1) that are several times longer than a plate (6) being attached (see Figure 3) in order to provide several protuberances on the shaft of the leg in order to aid in firmly holding the leg to the bone (column 5, lines 29-44). The device contains a central channel (11) that extends only partially through the leg in order to allow the device to be grasped with a tool. It would have been obvious to one skilled in the art at the time the invention was made to modify the legs taught by Mulhauser'772 with longer legs having a central channel extending partially through so that the device can be applied with a tool member.

It is old and well known to use flexible metal cover members to facilitate healing, as described by Kaikkonen (column 1, lines 65 to column 2, line 6), Because they are strong and tough and also capable of being ductile so they can be deformed and shaped to correspond to the surface topography of the tissue being fixed. It would have been obvious to one of ordinary skill in the art to modify the cover member taught by Mulhauser'772 in view of Frey'328 in order to have a strong and tough cover member that is also capable of being ductile.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LINDSEY BACHMAN whose telephone number is

(571)272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin T. Truong/
Primary Examiner, Art Unit 3734

/L. B./
Examiner, Art Unit 3734